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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

Complete if Known	
Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	~~Saoud, Christine J.~~
Attorney Docket Number	020167-000120US

U.S. PATENT DOCUMENTS

Examiner	Cite No.[1]	Document Number: Number Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
GM	AA	US-5,473,049	12/05/1995	Obermeier, et al.	
GM	AB	US-5,358,857	10/25/1994	Stengelin, et al.	
GM	AC	US-5,559,128	09/24/1996	Chakravarty, et al.	
GM	AD	US-5,719,021	02/17/1998	Inouye	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]	Number[4]	Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
GM	AE	EP	0 055 945		07/14/1982	Goeddel, et al.		☐
	~~AF~~	~~EP~~	~~0 347 781 B1~~		~~12/27/1989~~	~~Dörschug, et al.~~		☐
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Examiner Signature	GMichael	Date Considered	3/6/2003

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[1] **Applicant's** unique citation designation number **(optional)**. [2] Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 3

Complete if Known	
Application Number	09/423,100
Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	~~Saoud, Christine J.~~
Attorney Docket Number	020167-000120US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	AG	U. Shinde and M. Inouye, "Intramolecular chaperones and protein folding," *TIBS*, (1993), Vol. 18, pp. 442-446.	
	AH	M. Inouye, "Intramolecular Chaperone: The Role of the Pro-Peptide in Protein Folding," *Enzyme*, (1991), Vol. 45, pp. 314-321.	
	AI	M. Ikehara, et al., "Synthesis of a gene for human growth hormone and its expression in *Escherichia coli*," *Proc. Natl. Acad. Sci. USA*, (Oct. 1984), Vol. 81, pp. 5956-5960.	
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	AK	Norman and Litwack, "Pancreatic Hormones: Insulin and Glucagon," in *Hormones*, Academic Press, Inc., NY, (1987), pp 264-317.	
	AL	I. Johnson, "Human Insulin from Recombinant DNA Technology," *Science*, (Feb. 11, 1983), Vol. 219, pp. 632-637.	
	AM	D. Williams, et al., "Cytoplasmic Inclusion Bodies in *Escherichia coli* Producing Biosynthetic Human Insulin Proteins," *Science*, (Feb. 5, 1982), Vol. 215, pp. 687-689.	
	AN	R. Burgess, "Protein Purification," in *Protein Engineering*, Oxender, D.L., Fox, C.F., Eds.; Alan R. Liss, Inc, NY, (1987), pp. 71-82.	
	AO	R.E. Chance, et al., "The Production of Human Insulin Using Recombinant DNA Technology and a New Chain Combination Procedure," in *Peptides: Synthesis-Structure-Function*, Pierce Chem. Co., Rockford, Il, (1981), pp. 721-728.	
	AP	B.H. Frank and R.E. Chance, "The Preparation and characterization of human insulin of recombinant DNA origin," in Therapeutic Agents Produced by Genetic Engineering "Quo Vadis?" Symposium, (May 29-30, 1985), Sanoff Group, Toulouse-Labège, France, pp. 137-148.	
	AQ	R.E. Chance, et al., "Chemical, Physical, and Biological Properties of Recombinant Human Insulin," in J. L. Gueriguian *Insulins, Growth Hormone, and Recombinant DNA Technology*, Raven Press, NY, (1981), pp. 71-85	
	AR	R. D. Johnson, "The Processing of Biomacromolecules: A Challenge for the Eighties," *Fluid Phase Equilib.*, (1986), 29 109-123	
	AS	D. V. Goeddel, et al., "Expression in *Escherichia coli* of chemically synthesized genes for human insulin," *Proc. Natl. Acad. Sci. USA*, (Jan. 1979), No. 1, pp. 106-110.	

Examiner Signature		Date Considered	2/3/2003

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 3 of 3

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Filing Date	December 11, 2000
First Named Inventor	Gan, Zhong-Ru
Art Unit	1647
Examiner Name	~~Saoud, Christine J.~~
Attorney Docket Number	020167-000120US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	AT	J. P. Burnett, "Commercial Production of Recombinant DNA-Derived Products," in *Experimental Manipulation of Gene Expression*, Academic Press, NY, (1983), pp. 259-277.	
	AU	J. Etienne-Decent, "Regulation of Protein Synthesis," in *Genetic Biochemistry: From Gene to Protein*, Ellis Horwood Limited, Chichester, U.K., (1988), pp. 125-127.	
	AV	S. M. Wheelwright, *Protein Purification: Design and Scale up of Downstream Processing*, Oxford University Press, NY, (1991), p.217.	
	AW	B.H. Frank and R.E. Chance, "Two Routes for Producing Human Insulin Utilizing Recombinant DNA Technology," *Munch. Med. Wschr.*, (1983), Vol. 125, Suppl. 1, pp. S14-S20.	
	AX	E. P. Kroeff, et al, "Production Scale Purification of Biosynthetic Human Insulin by Reversed-Phase High-Performance Liquid Chromatography," *Journal of Chromatography*, (1989), Vol. 461, pp. 45-61.	
	AY	H. V. Tottrup and S. Carlsen, "A Process for the Production of Human Proinsulin in *Saccharomyces cerevisiae*," *Biotechnol. Bioeng.*, (1990), Vol. 35, pp. 339-348.	
	AZ	L. R. Castellanos-Serra, et al., "Expression and folding of an interleukin-2-proinsulin fusion protein and its conversion into insulin by a single step enzymatic removal of the C-peptide and the N-terminal fused sequence," *FEBS Letters*, (1996), Vol. 378, pp. 171-176.	
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	BB	L. Thim, et al., "Secretion and processing of insulin precursors in yeast," *Proc. Natl. Acad. Sci. USA*, (Sept. 1986), Vol. 83, pp. 6766-6770.	
	BC	I. V. Diers et al., "Yeast Fermentation Processes for Insulin Production," in Y. H. Chiu *Drug Biotechnology Regulations: Scientific Basis and Practices*, Marcel Dekker, Inc., NY, (1991), pp. 166-176.	
	BD	M. R. Ladisch and K. L. Kohlmann, "Recombinant Human Insulin," *Biotechnol. Prog.*, (1992), Vol. 8, pp. 469-478.	

Examiner Signature		Date Considered	3/6/2003

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FORM PTO-1449 (Modified)	Attorney Docket No.: 20167-000120US	Application No.: 09/423,100
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)	Applicant: Dr. Zhong-Ru Gan	
	Filing Date: October 29, 1999	Group: ~~1798~~ 1647

Reference Designation — **U.S. PATENT DOCUMENTS** — Page 1

Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
GW AA	6,001,604	12/14/99	Hartman et al.			
GW AB	4,916,212	04/10/90	Markussen et al.			
GW AC	4,342,832	08/03/82	Goeddel et al.			
GW AD	5,254,463	10/19/93	de Boer et al.			

FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-class	Translation (Yes/No)
GW AE	WO 96/20724	07/11/96	PCT			
GW AF	WO 97/18233	05/22/97	PCT			

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER G. Mueller — DATE CONSIDERED 3/6/2003

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